

Special Note: Co-Pending Application Recently Allowed

The Examiner's attention is drawn to related case USSN 08/436,670. This related case has been allowed, and the issue fee has been paid. Accordingly, the application will likely issue in the next few months. The Examiner's attention is further directed to U.S. patent 5,413,732, which is related to both the present case and to USSN 08/436,670.

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The Rejection Does Not Establish a *Prima Facie* Case of Obviousness

The Examiner alleges that the invention is obvious over Briggs *et al.*, U.S. Patent Number 3,932,943. Applicants traverse.

The rejection alleges that Briggs *et al.* disclose a spherical, highly porous, free flowing particle having a diameter of .84 mm in a vial, and that it would have been obvious to make particles of different diameters. *See*, Office Action at page 3.

With respect, the rejection does not address the limitations of the rejected claims. Independent claim 29 reads:

29. A container holding a dried chemical composition capable of dissolving in less than about 10 seconds in solution, wherein said dried chemical composition comprises a preselected precisely measured aliquot of said dried chemical composition.

The rejection does not explain how Briggs *et al.*, individually or in combination with the prior art, taught a "dried chemical composition capable of dissolving in less than about 10 seconds in solution" or how it taught a "preselected precisely measured aliquot of said dried chemical composition." Accordingly, the rejection is facially insufficient to establish a *prima facie* case of obviousness. Unless a *prima facie* case of obviousness can be established, the rejection must be withdrawn. *See*, the MPEP at § 2142.

Moreover, it is clear that Briggs *et al.* provide no logical basis for an obviousness rejection. The dissolution times for the Briggs *et al.* particles appears to have been 90-1200 seconds, which is certainly not equivalent to "about 10 seconds," as now claimed. *See*, Briggs *et al.*, column 9 at about line 5. Even the best dissolution times alleged (but not shown or taught) by Briggs *et al.* was more than twice those now claimed, at 20-30 seconds. *See*, column 4, line 65.

Furthermore, Briggs *et al.* taught away from making dried spheres with a diameter of greater than 1 mm, as now claimed, e.g., in claim 31. Briggs *et al.* teach that

the "resulting product consists of free flowing spheres having at least 90% pores and *preferably not exceeding 1mm in diameter.*" See, column 5, lines 19- 21, *emphasis added.* The reason for this size limitation is that the method of making allegedly "uniform" spheres by the Briggs *et al.* method (i.e., spraying the cryogenic liquid through a needle) breaks down as the size of the dried spheres increase, as clearly indicated by Briggs *et al.*:

Using a needle with a gauge larger than 16 produces sufficiently large particles that they tend to fracture, which may reduce their free flowing and ease of handling. Additionally, product homogeneity is better assured if the particles are not fractured.

See, Briggs *et al.* at column 3, line 16-21. Thus, Briggs *et al.* expressly taught away from making larger particle sizes, as claimed in claim 31. It is well settled that an express teaching away from achieving an invention is strong evidence of non-obviousness. See, *United States v. Adams et al.*, 383 U.S. 39 (1966). See also, the MPEP at § 2144.

It is also well settled law that if it is necessary to modify the teachings of a prior art reference in a manner that would render the prior art inoperable to achieve an invention, then such a modification would generally not be obvious. See, *In re Kramer* (Fed. Cir. 1991) 18 USPQ2d at 1416, citing *In Re Gordon* (Fed. Cir. 1984) 221 USPQ 1125 at 1127. In the present case, the Examiner alleged that it would have been obvious to make larger particles using the Briggs *et al.* methods. However, as evidenced by the passage above, the procedure taught by Briggs *et al.* cannot be used to make uniform particles larger than 1 mm in diameter. Thus, the modification of Briggs *et al.* apparently relied upon by the Examiner for making larger particles *would not work.*

It is basic patent law that establishing a *prima facie* case of obviousness requires clear reasoning or evidence showing how the prior art provides both a motivation to achieve the invention and an expectation that the invention will work. See, *In re Vaeck*, 20 USPQ2d 1438 (Fed. Cir. 1991) and the MPEP at § 2143 - § 2143.03. In the present case, the rejection does not explain how the prior art relates to the claimed invention. Furthermore, as evidenced by the fact that the cited art expressly taught away from the invention, no suggestion or motivation to achieve the invention can be drawn from the cited art. Moreover, as evidenced by the fact that the methods of making spheres provided in the cited art are demonstrated in the cited art to be non-operable for making spheres with the

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size ranges claimed, e.g., in claim 31, it is clear that the cited art provides no expectation that the combination suggested by the Examiner would work. Accordingly, the rejection should be withdrawn.

In view of the foregoing, Applicants believe all claims now pending in this application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at (415) 576-0200.

Respectfully submitted,



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